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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,814	08/26/1998	MASAHIKO DOHI	Q51505	8214

7590 10/03/2003
SUGHRUE MION ZINN MACPEAK & SEAS
2100 PENNSYLVANIA AVENUE N W
WASHINGTON, DC 20037

EXAMINER

WELLS, LAUREN Q

ART UNIT PAPER NUMBER

1617

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/125,814

Applicant(s)

DOHI ET AL.

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 51-66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 40.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 51-66 are pending. The Amendment filed 9/8/03, Paper No. 42, amended claims 51, 59, 61 and 63, and cancelled claim 67.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed 9/8/03 (Paper No. 42) to the rejection of claims 51-66 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive.

Applicant's arguments and amendment to the claims filed 9/8/03, Paper No. 42, are sufficient to overcome the 35 USC 112 rejections in the previous Office Action.

103 Rejection Maintained

The rejection of claims 51-57, 59-67 under 35 U.S.C. 103(a) as being unpatentable over is MAINTAINED for the reasons set forth in the Office Action mailed 5/7/03, Paper No. 39, and those found below.

Applicant argues, "in the Declaration filed March 14, 2001, Applicants compared the present invention (Example 74) to a composition corresponding to the composition of Suzuki (Comparative Example 67)". This argument is not persuasive, as this declaration is not persuasive to show unexpected results of the instant invention over that of the closest prior art, Suzuki et al. First, the Examiner respectfully points out that Comparative Example 67 does not seem to correspond to any of the Examples of Suzuki. Second, the Examiner respectfully points out that on page 8 of the Declaration the present invention is compared to Example 1(b) of Suzuki. However, this is not persuasive, as Example 1(b) of Suzuki does not contain a cellulose as the water-absorbing and gel-forming base materials, though Suzuki teaches celluloses as base

materials in the body of his reference. Thus, it is not possible to compare Example 1(b) of Suzuki with the composition of the instant invention.

Applicant argues, "in the Declaration filed October 22, 2001, Applicants compared compositions of the present invention prepared by the processes of the present invention to a composition obtained by the processes disclosed by Suzuki. For Example, Applicants compared Examples 75, 76 and 77 to Comparative Example 68 (made by a process disclosed by Suzuki)". This argument is not persuasive. First, it is not clear that Comparative Example 68 is a method taught by Suzuki. What method example in Suzuki corresponds to Comparative Example 68 in the instant specification? As a result, this declaration is not persuasive. Again, the Examiner respectfully points out that it is impossible to compare the examples of Suzuki with those of the instant invention, as Suzuki does not exemplify a composition comprising both the preferred water-absorbing/gel-forming base and water-absorbing/water-insoluble base, though he teaches this combination.

Applicant argues, "obtaining a composition comprising a drug, a water-insoluble base, and a water-soluble base, wherein the drug is dispersed more on the water-insoluble base material involved more than routine skill. . .as shown by the Examples and the Declaration, the composition of the present invention having more drug adhered on the water-insoluble base material are obtained by specific processes that are neither taught nor suggested in Suzuki". This argument is not persuasive. As pointed out in the previous Office Action, Suzuki discloses at col. 5, lines 53-65 that the drug may be adhered to or dispersed in the water-insoluble base. Suzuki does not teach that he drug is adhered to or dispersed in the gel-forming base. Therefore,

even with the addition of a gel-forming base, it is reasonable to expect that the drug would be more adhered to or dispersed in the water-insoluble base.

Applicant argues, "there is no teaching in Suzuki that would lead one of ordinary skill in the art to obtain the composition of the present invention using the various methods of the present invention". This argument is not persuasive. Again, as pointed out in the previous Office Action, the instant claims are product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

Applicant argues, "Applicants have provided facts that the drug adheres more to the water-absorbing and water-soluble base when the drug is freeze-dried with the water-absorbing and water-soluble base material. For example, in the Declaration submitted on February 24, 2002, Applicants submitted photographs showing the adherence of drug to the base materials, and explained how the yellowish color/stain from the drug on the bases corresponds to the amount of drug adhered to the bases". This argument is not persuasive. First, this argument is not commensurate in scope with the instant independent claims, which do not recite a method of freeze-drying. Second, the Examiner is unable to find any photographs submitted with the Declaration of 2/22/00. The Examiner respectfully points out that this Declaration was faxed. Thus, it is not clear how photographs could have been attached.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

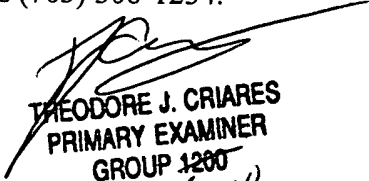
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw


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